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DEPARTMENT OF HEALTH & HUMAN SERVICES

2/10/98 EB

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

February 9, 1998

WARNING LETTER

Mr. William R. Pickett, Owner
Rockwood Industries d/b/a/
Franklin Pharmaceuticals
4240 Blue Ridge Blvd., Suite 350
Kansas City, MO 64113

Ref.# - 98-KAN-008

Dear Mr. Pickett:

This letter is written in reference to your firm's marketing and distribution of "A Natural Alternative to Phen-Fen Herbal Supreme". Your product is labeled as an alternative to the combination of the prescription drugs, fenfluramine and phentermine, which is commonly known as "Fen-Phen". These prescription drugs are intended to treat obesity. Labeling your product as an alternative to Fen-Phen (fenfluramine and phentermine), suggests that it is intended for the same uses as phentermine and fenfluramine. Thus, you are representing "A Natural Alternative to Phen-Fen Herbal Supreme" as a treatment for obesity. In this regard, "A Natural Alternative to Phen-Fen Herbal Supreme" is a drug as defined in Section 201(g)(1)(B) of the Federal Food, Drug and Cosmetic Act (the Act). Labeling is not limited to the immediate product containers but includes all promotional literature which you distribute in connection with your products.

"A Natural Alternative to Phen-Fen Herbal Supreme" is also a "new drug" under Section 201(p) of the Act based on: 1) the trade name, "A Natural Alternative to Phen-Fen Herbal Supreme", and 2) the lack of any evidence that this product is generally recognized as safe and effective for the treatment of obesity.

Since this drug is a "new drug," it may not be legally marketed in the United States without an approved new drug application (Section 505(a)of the Act).

Also, this drug is misbranded because its labeling fails to bear adequate directions for use (Section 502(f)(1)of the Act) and further the labeling is false and misleading since it suggests

that the product is recognized as safe and effective for the intended use (Section 502(a) of the Act) and this is not the case.

This letter is not intended to be an all inclusive review of all labeling and products your firm markets. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations.

We request that you take prompt action to correct these violations. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. These actions may include seizure and/or injunction.

Please notify this office in writing within fifteen (15) working days of receipt of this letter as to the specific steps you have taken to correct the stated violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District